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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,408	06/22/2005	Avindra Nath	50229-444	8400

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
09/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,408	NATH ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *1-32 and 43-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-36 and 52* is/are rejected.

7)☒ Claim(s) *37-42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/03/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 31 October, 2007. Applicants election of Group IV (claims 33-42 and 52) with traverse is noted. Applicants argue that Groups IV and V should be rejoined since it would not constitute and undue burden to examiner both groups concomitantly. These arguments have been carefully considered but are not deemed to be persuasive for the reasons of record articulated in the original restriction requirement. Accordingly, the requirement is still deemed to be proper and is therefore made **FINAL.** Applicants are reminded that upon the identification of allowable subject matter, the rejoinder of Groups IV and V may be requested. Claims 1-32 and 43-51 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

35 U.S.C. § 119(e) or § 120 Benefit

Applicant is advised that if the benefit of a prior-filed application under 35 U.S.C. § 120 is desired, a specific reference to the prior-filed application in compliance with 37 C.F.R. § 1.78(a) **must** be included in the first sentence(s) of the specification following the title **or** in an application data sheet. For benefit claims under 35 U.S.C. § 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. If the instant application is a utility or plant application filed under 35 U.S.C. § 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the

application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. § 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. § 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 C.F.R. § 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. § 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. § 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. § 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. § 120 or 119(e) and 37 C.F.R. § 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 C.F.R. § 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 C.F.R. § 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. If the reference to the prior application was previously submitted

within the time period set forth in 37 C.F.R. § 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 C.F.R. § 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 C.F.R. § 1.78(a) and the surcharge under 37 C.F.R. § 1.17(t) are not required. **Applicant is still required to submit the reference in compliance with 37 C.F.R. § 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See M.P.E.P. § 201.11. It is suggested that applicants amend the first paragraph of the specification to include any relevant priority claims.**

37 C.F.R. § 1.98

The information disclosure statement filed 03 March, 2005, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33 and 52 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Buanec *et al*. (2001). The claims are simply directed toward a Tat-absorbed nanoparticle or delivery system comprising said particles. Buanec and colleagues provide HIV-1 Tat-absorbed nanoparticles (see Abstract, p. 316) and delivery systems comprising said particles (see MATERIALS AND METHODS, *Immunogen preparations* and *Immunization protocols*, p. 317). This teaching meets all of the claimed limitations.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cui and Mumper (2002) in view of Vives *et al*. (1994) and Rossi *et al*. (1997). The claimed invention is directed toward Tat-absorbed nanoparticles comprising amino acids 1-72 or 1-86 of wildtype Tat, or a C22G Tat mutant. Cui and associated provide anionic nanoparticles engeineered from oil-in-water micoremulsion precursors. These particles were coated with a protein and administered to animals wherein it was demonstrated that they product a strong Th1 and Th2 immune

response (see Abstract, p. 229). This teaching does not disclose the preparation of Tat-absorbed nanoparticles. Vives and associates provide numerous Tat proteins and polypeptides including, *inter alia*, Tat_{1-72} and Tat_{1-86} (see Abstract, p. 3343). Rossi and coworkers provide yet another Tat variant comprising a C22G mutation. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to utilize the Tat peptides and polypeptides of Vives *et al*. (1994) and Rossi *et al*. (1997), in the nanoparticle preparative methodologies of Cui and Mumper (2002), since this would result in Tat-absorbed nanoparticles that are highly immunogenic. One of ordinary skill in the art would have been motivated to generate these particles to facilitate the development of immune reagents against both HIV-1 and -2 Tat.

Claim Objections

Claims 37-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner’s RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related

correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin, Ph.D./
Primary Examiner, Art Unit 1648

06 September, 2008